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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/187,879	01/27/94	ROBINSON H	UMMC9103A2

HM12/0713

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EXAMINER	
CLARK, D	
ART UNIT	**PAPER NUMBER**
1633	36

DATE MAILED: 07/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/187,879	Robinson et al.
Examiner	**Group Art Unit**
Deborah Clark	1633

☒ Responsive to communication(s) filed on *May 28, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *44-51, 62-64, 67-72, 74, and 78-89* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *44-51, 62-64, 67-72, 74, and 78-89* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 ✓

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *35* ✓

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Applicant's amendment and response to the prior office action has been received and entered, 05/28/99, paper no. 34. Claims 44-51, 62-64, 67-72, 74, and 78-89 remain pending.

Claim Rejections - 35 USC § 112

2. Claims 44-51, 62-64, 67-72, 74, and 78-89 stand rejected under 35 USC 112, 1st paragraph for reasons of record.

Applicants traverse the rejection making three points, each of which is responded to in turn as set forth in paper no. 34.

The constructs:

Applicants argue that the constructs used in the declaration are similar to, or essentially the same as, the constructs used in the specification (see paper no. 34, pages 4-6). However, the constructs used in the declaration are different epitopes than those used in the specification and cannot be correlated. It is recognized that the "backbones" were made in the same way and that the sgp# refers to the size of the protein. However, it is not the "backbone" that is to induce the immune response, but rather the epitope. The epitope used is a critical factor in the production of the response. Therefore, this argument is non-persuasive.

Protectivity of the constructs:

Applicants point out that "immunizing" refers to production of an immune response which protects, partially or totally, from the manifestations of infection (i.e., disease) caused by the infectious agent. And, that the declaration describes such an immune response demonstrated by a reduction in viral load and animals free of clinical signs of AIDS at the time of euthanasia (see paper no. 34, page 6). However, the declaration clearly acknowledges by week 12 that the control group achieved similar reductions in viral load (see declaration, page 15, last ¶). More importantly, the CD4+ cells declined in both groups (see declaration page 17). Further, though the four monkeys in the multiple route did not have clinical signs of AIDS at the time of euthanasia, neither did one of the two (50%) of the control monkeys. Furthermore, the trial was terminated at one year post-challenge. The time for the AIDS progression can be much longer than one year. The challenge virus was an uncloned SIVmac251 virus. Johnson et al. states that it typically takes longer than one year for AIDS progression where the virus is other than a 239 clone (see applicant's AX2, the explanation for Table 1 appearing on page 58). Therefore, it is not clear that these animals had any level of protection from disease manifestation.

Models:

Applicants argue that the macaque model is accepted as an important animal model for infection of humans with HIV and provide three references, published in or around the early 1990's, to support that point (see paper no. 34, ¶ bridging pages 6-7). However, the macaque model is not recognized as predictive for HIV vaccination. For instance, in 1998 Cohen and Fauci recognized that there is a lack of correlates of protective immunity in HIV infection and

go one to state that the SIV model provides "clues" (see Cohen and Fauci, JAMA editorial, page 88 col. 1), in 1994 Gilboa and Smith recognized that one drawback to using SIV infected macaques is the difference in the biology of SIV and HIV (see Gilboa and Smith, TIG, ¶ bridging pages 141-142), and in 1996 Glaser reports that no good animal model exists (see Glaser, Genetic Engineering News, page 6, col. 2 (it should be noted that page 6 had to be copied onto two pages)). Therefore, it is clear that SIV infected macaques is not an art accepted model of HIV infected humans.

3. Claims 47-49 and 71-72 stand rejected under 35 USC 112, 2nd paragraph for reasons of record. Applicants have amended the claims to remove the term "represents". However, claims 47-49 and 71-72 require that the antigens be from different phases of infection, from viruses having different tropisms, or viruses having different routes of transmission, or an env protein having a different route of transmission. Applicants state that the specification describes that the env protein undergoes a marked evolution in infected humans and may vary depending on the subgroup, phase, tropism or route. These claims remain indefinite. They are not limited by which antigens are encompassed. For instance, claim 48 requires that the antigens have a different tropism, the examiner believes that the prior art supports that the env protein is responsible for the tropism, however, the claim is not limited to the env protein. Further, the claims do not read well. The way that the claims are stated, it sounds as though the envs are different proteins. Much as the GaLV env is different from the HIV env. The claims should be clarified.

Claim Rejections - 35 USC § 103

4. The previously made rejection under 35 USC 103 is withdrawn because it is agreed that the disclosure would have been non-enabling over the claimed invention because the claimed invention requires that the mammal be protected from disease and mice, the model used by Wolf and Felgner, do not develop AIDS.

Conclusion

5. No claim is allowed.

6. The claims are free of the prior art of record for reasons of record or as discussed above.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on (703) 308-2801. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DRC

07/07/99

Bruce Campell

BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800